JUL 29 2011

SECTION II. 510(K) SUMMARY

A. Device Name

Proprietary Name:	GlideCross Support Catheter
Classification Name:	Percutaneous catheter 21 CFR 870.1250 Class II
Common Name:	Percutaneous catheter
Product Code:	DQY
Panel:	Cardiovascular

B. Intended Use

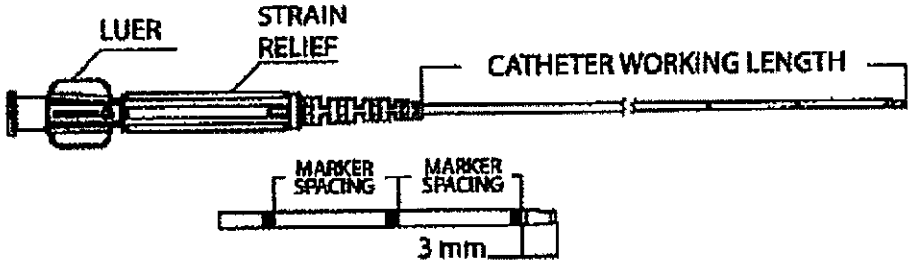
The GlideCross™ Support Catheter is intended to be used for guide wire support during access of the vasculature allowing for exchange of guide wires and provides for the delivery of saline and/or diagnostic contrast agents. The GlideCross™ Support Catheter is indicated for use in the peripheral vasculature.

C. Device Description

The GlideCross Support Catheters are single lumen intravascular catheters designed for use in the peripheral vasculature. The catheters provide support to guide wires during access of the vasculature and allow for exchange of guide wires while maintaining vessel access. The GlideCross Support Catheters are available in 9 models compatible with various guide wire sizes and have a lubricous hydrophilic coating on the distal shaft and a female Luer on the proximal end. The catheters have 3 encapsulated radiopaque marker bands evenly spaced along the distal shaft, with the distal band 3 mm from the tip, to aid in positioning of the catheter tip and in estimating distances.

Device Specifications:

Model #	54-143	54-145	54-189	54-183	54-185	54-156	54-159	54-153	54-155
Maximum Guidewire, inch/mm	0.014 / 0.36	0.014 / 0.36	0.018 / 0.46	0.018 / 0.46	0.018 / 0.46	0.035 / 0.89	0.035 / 0.89	0.035 / 0.89	0.035 / 0.89
Working Length, cm	135	150	90	135	150	65	90	135	150
Minimum Guidewire length, cm	180	180	150	180	180	150	150	180	180
Marker Band Spacing, mm	15	15	15	15	15	50	50	50	50
Proximal Shaft Diameter, inch/mm	0.063 / 1.60	0.063 / 1.60	0.063 / 1.60	0.063 / 1.60	0.063 / 1.60	0.063 / 1.60	0.063 / 1.60	0.063 / 1.60	0.063 / 1.60
Distal Shaft Diameter, inch/mm	0.029 / 0.74	0.029 / 0.74	0.033 / 0.84	0.033 / 0.84	0.033 / 0.84	0.051 / 1.30	0.051 / 1.30	0.051 / 1.30	0.051 / 1.30
Tip Outside Diameter, inch/mm	0.019 / 0.48	0.019 / 0.48	0.024 / 0.61	0.024 / 0.61	0.024 / 0.61	0.040 / 1.02	0.040 / 1.02	0.040 / 1.02	0.040 / 1.02
Hydrophilic Coating Length, cm	60	60	60	60	60	40	60	60	60
Minimum Introducer Sheath, French	5	5	5	5	5	5	5	5	5



D. Reason for Premarket Notification

This premarket notification is being submitted for the GlideCross Support Catheter which is a new device being manufactured by Terumo Medical Corporation.

E. Statement of Equivalence

The GlideCross Support Catheter submitted in this 510(k) is substantially equivalent in intended use, design, technology/principles of operation, materials, and performance to the Spectranetics QUICK CROSS CATHETERS cleared under K033678 [1].

F. Principle Of Operation / Technology

The GlideCross Support Catheter is operated manually or by a manual process.

During an interventional or diagnostic procedure, the physician will follow the standard procedure of placing a guide wire and introducer within a vessel. Then a guiding catheter or sheath would be advanced over the guide wire. Next, the GlideCross Support Catheter would be inserted over the guide wire and through the hemostasis valve of the guiding catheter or sheath. The guide wire and GlideCross Support Catheter would then be advanced to the target vessel. The GlideCross Support Catheter can then be used for injection of contrast media or for support and exchange of guide wires.

[1] A statement of substantially equivalence to another product is required by 21CFR807.87, and relates only to whether the present product can be marketed without prior reclassification or clinical approval. The present submission is therefore not related to the coverage of any patent, and is not to be interpreted as an admission or used as evidence in a patent infringement lawsuit. As the Commissioner of the FDA has stated, "...a determination of substantial equivalence under the federal Food, Drug, and Cosmetic Act relates to the fact that the product can lawfully be marketed without pre-market approval or reclassification. This determination is not intended to have any bearing whatever on the resolution of patent infringement suits" 42 Fed. Reg. 42,520, et seq. (1977)

G. Design / Materials

The GlideCross Support Catheter in this submission uses similar materials as the predicate devices. Differences in materials between the devices do not raise any new issues of safety and effectiveness. Below is a table with a comparison of the materials used in the GlideCross Support Catheter and the predicate devices:

		QUICK CROSS CATHETERS	Terumo GlidCross Support Catheter
		K033678	—
Design	Construction	Single layer	Two layers distal section, One layer on proximal section
	Number of Radiopaque markers	3	3
Material	Inner layer	Polyethlene	Polyester elastomer (Pebax)
	Outer layer	-	Polyester elastomer (Pebax)
	Radiopaque marker	Platinum	Platinum alloy

H. Specifications

The Terumo GlideCross Support Catheter submitted in this 510(k) and the Spectranetics QUICK CROSS CATHETERS cleared under K033678 have similar device specifications. Differences in specifications between the devices do not raise any new issues of safety and effectiveness.

Item	QUICK CROSS CATHETERS K033678	Terumo GlideCross Support Catheter
Effective lengths	65, 90, 135, 150 cm	65, 90, 135, 150 cm
Number of radiopaque markers	3	3
Distance from distal tip to first radiopaque marker	3mm	3mm
Radiopaque marker spacing	15mm (for 0.014 &0.018 wire compatible catheters) 50mm (for 0.035 wire compatible catheter)	15mm (for 0.014 &0.018 wire compatible catheters) 50mm (for 0.035 wire compatible catheter)
Guidewire Compatibility	0.014, 0.018, 0.035 inch	0.014, 0.018, 0.035 inch
Maximum Injection Pressure	300psi	300psi
Minimum Introducer Sheath Compatible With	4Fr-5Fr depending on model number	5Fr
Tip design/shape	Straight	Straight
Hydrophilic Coating	Distal 40cm	Distal 40-60cm

I. Performance

The Terumo GlideCross Support Catheter submitted in this 510(k), and the Spectranetics QUICK CROSS CATHETERS cleared under K033678 have similar performance characteristics. The following performance tests were conducted on these catheters. Testing was performed on the Terumo GlideCross Support Catheters and the Spectranetics QUICK CROSS CATHETERS.

1) Trackability
2) Wire Support
3) Pushability/Crossability
4) Lubricity

The performance of the Terumo GlideCross Support Catheter is substantially equivalent to the performance of the predicate devices.

In addition, the following tests were performed on the Terumo GlideCross Support Catheter to assure proper performance. All test results met the pre-approved specifications.

1) Simulated use
2) Length
3) Penetration
4) Visual inspections-Catheter Tip
5) Visual inspections- Marker bands
6) Visual appearance / foreign matter
7) Outer diameter: Catheter tip
8) Outer diameter: Proximal shaft
9) Flow rate
10) Catheter burst
11) Inner diameter: Hub
12) Inner diameter: Catheter tip
13) Luer taper
14) Luer assembly
15) Luer resistance to overriding
16) Force at break
17) Kink resistance
18) Catheter leakage
19) Marker spacing
20) Coating length
21) Coating Integrity and Particulate Release Verification
22) Torque Testing

J. Additional Safety Information

Biocompatibility testing was conducted in accordance with the FDA General Program memorandum #G95-1 (5/1/95): Use of International Standard ISO 10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" and ISO 10993-1:2009, "Biological Evaluation of Medical Devices Part 1: Evaluation and testing within a risk management process."

GlideCross Support Catheter is classified as Externally Communication Device, Circulating Blood, Limited Contact (up to 24 hours). The Terumo Support Catheter successfully passed all of the following biocompatibility tests:

Biocompatibility Testing on non-aged, 2x EO sterile GlideCross Support Catheter			
Test/Details	Details (if applicable)	Standard	Result
Physicochemical profile		USP <661>	Meets Requirements
Cytotoxicity- L929 Neutral Red Uptake- ISO	L929 Neutral Red Uptake	ISO 10993-5	Not considered to have cytotoxic potential
Hemolysis	Direct Contact	ASTM F756	Non-hemolytic
In vitro Hemocompatibility Assay – ISO Direct Contact	Direct Contact	ISO 10993-4	Pass
Thrombogenicity Study in Dogs		ISO 10993-4	Thrombosis was not considered significant
Complement Activation	C3a & SC5b-9, Direct Contact	ISO 10993-4	Meets Requirements
Unactivated Partial Thromboplastin time	Direct Contact	ISO 10993-4	Meets Requirements
Prothrombin Time	Direct Contact	ISO 10993-4	No adverse effect on the prothrombin time of human plasma
Sensitization	Kligman Maximization, NaCl and CSO extracts	ISO 10993-10	Meets requirements
Intracutaneous Reactivity	Intracutaneous Injection, NaCl and CSO extracts	ISO 10993-10	Meets requirements
Acute Systemic Toxicity	Systemic Injection, NaCl and CSO extracts	ISO 10993-11	Negative
Pyrogenicity	Rabbit Pyrogen, Material Mediated	ISO 10993-11	Meets Requirements
Genotoxicity	Reverse mutation assay, *Salmonella typhimurium* and *Escherichia coli*	ISO 10993-3	Not considered to be mutagenic

In addition, limited screening tests were conducted on the accelerated aged, 2x EO sterile device to demonstrate that aging does not affect the device's biocompatibility. The results are summarized in the table below.

Biocompatibility Testing on aged[1], 2x EO sterile GlideCross Support Catheter			
Test	Details (if applicable)	Standard	Result
Physicochemical profile		USP <661>	Meets Requirements
Cytotoxicity	L929 Neutral Red Uptake	ISO 10993-5	Not considered to have cytotoxic potential
Hemolysis	Direct Contact	ASTM F756	Non-hemolytic

The sterilization conditions have been validated according to ISO 11135, *Sterilization of Health Care Products– Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices* to provide a Sterility Assurance Level (SAL) of 10^{-6}.

Residual ethylene oxide (EO) and ethylene chlorohydrin (ECH) residuals will meet requirements for limited exposure devices (contact up to 24 hours) prior to use based on ISO 10993-7, *Biological Evaluation of medical devices- Part 7: Ethylene Oxide Sterilization residuals*. Residual EO will not exceed 4 mg per device and residual ECH will not exceed 9 mg per device.

The GlideCross is certified to be non-pyrogenic in the unopened and undamaged package. Kinetic Turbidimetric Limulus Amebocyte Lysate (LAL) test is performed on each lot of production accordance to the United States Pharmacopoeia (USP) <85> Bacterial Endotoxins Test. Validation was performed in accordance with FDA published "Guideline on Validation of the Limulus Amebocyte Lysate Test as an End-Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products, and Medical Devices"; 1987.

I. Substantial Equivalence

The Terumo GlideCross Support Catheter submitted in this 510(k) is substantially equivalent in the general intended use, design, technology/principles of operation, materials, and performance to the Spectranetics QUICK CROSS CATHETERS cleared under K033678. Differences between the devices do not raise any issues of safety or effectiveness.

J. Submitter Information

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Date Prepared: June 3, 2011

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Terumo Medical Corp.
% Mark Unterreiner
950 Elkton Blvd
Elkton, MD 21921

JUL 29 2011

Re: K111556
Trade/Device Name: GlideCross Support Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: DQY
Dated: June 3, 2011
Received: June 6, 2011

Dear Mr. Unterreiner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111556

Device Name: GlideCross Support Catheter

Indications For Use:

The GlideCross™ Support Catheter is intended to be used for guide wire support during access of the vasculature allowing for exchange of guide wires and provides for the delivery of saline and/or diagnostic contrast agents. The GlideCross™ Support Catheter is indicated for use in the peripheral vasculature.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K111556